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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,992	02/28/2002	Brian Reynolds	1001.1524102	8402

28075 7590 06/01/2005

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EXAMINER	
MARMOR II, CHARLES ALAN	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 06/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/086,992	REYNOLDS ET AL.	
	Examiner	Art Unit	
	Charles A. Marmor, II	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50 and 52-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *54-58* is/are allowed.

6)☒ Claim(s) *1-12,16,20-27,33-37,39-50,52 and 53* is/are rejected.

7)☒ Claim(s) *13-15,17-19,28-32 and 38* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02282005; 04042005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed February 28, 2005. The Examiner acknowledges the amendments to claims 1, 9, 10, 20-23, 25, 27, 35, 39, 40, 43, 47 and 54. Claims 1-50 and 52-58 are pending.

Claim Objections

2. Claim 5 is objected to because of the following informalities: the claim apparently should read -- A guidewire as in claim 3, wherein the reduced size portions have at least one of a taper and an interlocking shape--. Appropriate correction is requested.

3. Claim 46 is objected to because of the following informalities: in line 2, "an first" and "an second" should read --a first-- and --a second--, respectively. Appropriate correction is required.

4. Claim 52 is objected to because of the following informalities: in line 2, "an first" and "an second" should read --a first-- and --a second--, respectively. Appropriate correction is required.

5. Claim 56 is objected to because of the following informalities: in line 1, --the-- should be inserted before "polymer". Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 43-50, 52 and 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Rooney et al. ('105). Rooney et al. teach a guidewire including a core wire (20) having a proximal portion and a distal portion; a coil (30) having a proximal region and a distal region; and an outer structure disposed about the core wire and the coil. The core (20), including the distal portion thereof, may be formed of a linear elastic nickel titanium alloy (col. 3, lines 37-39). The proximal region of the coil is connected to the distal portion of the core wire and the distal region of the coil extends distally beyond the distal portion of the core wire (Fig. 2). The outer structure is formed by a pair of polymeric sheathes. A first polymer sheath (40) extends distally beyond the distal portion of the core wire and the distal region of the coil to form a tip. A second polymer sheath is formed by a polymer coating that coats the entire length of the guidewire (col. 5, lines 10-13), such that the second polymer sheath will extend proximally beyond the proximal region of the coil. The outer structure may also include an outer coil disposed around the coil (col. 4, lines 1-13). The coils may be flat wire coils or round wire coils (col. 2, line 50). The coil may act as a safety structure. The core is wrapped around the entire length of the core which may include a tapered section (col. 3, lines 52-54). Although the coil is "preferably" not

wrapped around the tapered core, this statement implies that the coil may be wrapped around the tapered core, in which case the coil would taper in a distal direction such that the coil would have a first outer diameter that differs from a second outer diameter.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1, 3-6, 9-12, 16, 23, 24, 35-37, 39 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abrams et al. ('818) in view of Sahatjian et al. ('004).

Abrams et al. teach a guidewire having a proximal section (11) formed of stainless steel (col. 9, lines 56-61), a distal section (12) formed of a superelastic nickel titanium alloy (col. 6, lines 62-65), and a connector (13) disposed about and welded to the proximal end of the distal section and the proximal end of the distal section (col. 6, lines 12-16). The connector is a tubular

member that may be formed of nickel-chromium alloy, cobalt alloy or nickel-chromium-iron alloy (col. 4, lines 54-63) and col. 6, line 62 - col. 7, line 3). Reduced size portions having a taper and uniform profile, as well as are illustrated in Figure 1. An outer structure comprising a coil (17) is disposed about and extends beyond the distal section (see Figure 1). Abrams et al. teach all of the limitations of the claims except that the distal section of the guidewire is formed of a linear elastic nickel titanium alloy.

Sahatjian et al. teach that linear elastic nickel titanium alloys and superelastic nickel titanium alloys are known to be interchangeable as materials for forming a core of a guidewire. Sahatjian et al. teach that linear elastic alloys are advantageous because it is highly flexible yet stiff enough to resist kinking and can be shape-set for ease in steering the guidewire into a highly tortuous or desired curved passageway (Abstract and col. 6, lines 41-47).

It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to form the superelastic nickel titanium alloy distal section of a guidewire similar to that of Abrams et al. of a linear elastic nickel titanium alloy as a design choice in view of the teachings of Sahatjian et al. in order to provide the guidewire with a distal section that is highly flexible yet stiff enough to resist kinking and can be shape-set for ease in steering the guidewire into a highly tortuous or desired curved passageway.

10. Claims 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jafari ('082) in view of Sahatjian et al. ('004).

Jafari teaches a guidewire having a proximal section (11) formed of stainless steel (col. 8,

lines 38-45), a distal section (12) formed of a psuedoelastic nickel titanium alloy (col. 6, lines 61-65), and a means for joining (20) the proximal section to the distal section formed from a metal alloy different from the materials of the proximal section and the distal section (col. 5, lines 56-60). Jafari teaches all of the limitations of the claims except that the distal section of the guidewire is formed of a linear elastic nickel titanium alloy.

Sahatjian et al. teach that linear elastic nickel titanium alloys and superelastic nickel titanium alloys are known to be interchangeable as materials for forming a core of a guidewire. Sahatjian et al. teach that linear elastic alloys are advantageous because it is highly flexible yet stiff enough to resist kinking and can be shape-set for ease in steering the guidewire into a highly tortuous or desired curved passageway (Abstract and col. 6, lines 41-47).

It would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to form the superelastic nickel titanium alloy distal section of a guidewire similar to that of Jafari of a linear elastic nickel titanium alloy as a design choice in view of the teachings of Sahatjian et al. in order to provide the guidewire with a distal section that is highly flexible yet stiff enough to resist kinking and can be shape-set for ease in steering the guidewire into a highly tortuous or desired curved passageway.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-3, 5, 7-11, 20-27 and 33-42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 8, 9, 12-14, 18 and 24 of copending Application No. 09/972,276. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the co-pending application "anticipate" the claims of the instant application. The claims of both applications recite a guidewire having a proximal section formed of a metal (stainless steel); a distal section formed of a linear elastic nickel-titanium alloy (paragraph [0015] of the co-pending application discloses that the nickel-titanium alloy claimed therein is intended to encompass both super elastic and linear elastic alloys); and a connector formed of a material different from the respective materials of the proximal and distal portions of the guidewire, and specifically, nickel-chromium alloy or nickel-molybdenum alloy.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

13. Claims 54-58 are allowed over the prior art of record.

14. Claims 13-15, 17-19, 28-32 and 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 13-15, no prior art of record teach a guidewire including a proximal section; a distal section including a linear elastic nickel-titanium alloy; and a connector for permanently joining the distal end of the proximal section and the proximal end of the distal section formed of a nickel-chromium alloy, a nickel-molybdenum alloy, or a cobalt alloy, where a polymer sleeve is disposed about the distal section.

Regarding claims 17-19, no prior art of record teach a guidewire including a proximal section; a distal section including a linear elastic nickel-titanium alloy; and a connector for permanently joining the distal end of the proximal section and the proximal end of the distal section formed of a nickel-chromium alloy, a nickel-molybdenum alloy, or a cobalt alloy, where an inner coil is disposed about the distal section and at least partially within a first coil such that the distal portion of the inner coil extends distally of the distal section.

Regarding claims 28-32, no prior art of record teach a guidewire including a proximal section; a distal section including a linear elastic nickel-titanium alloy; and a connector for permanently joining the distal end of the proximal section and the proximal end of the distal section formed of a N006625 metal alloy, a N10276 metal alloy, or a B2 nickel-molybdenum alloy, where at least one of a polymer sleeve or a coil is disposed about the distal section.

Regarding claims 54-58, no prior art of record teach a guidewire including a proximal

section; a distal section including a linear elastic nickel-titanium alloy; and a connector for joining the distal end of the proximal section and the proximal end of the distal section that is welded to at least the distal section and formed of a nickel-chromium alloy, a nickel-molybdenum alloy, or a cobalt alloy, where an inner coil is disposed about the distal section such that the proximal portion of the inner coil is connected to the distal end of the distal section and the distal portion of the inner coil extends distally of the distal section, and where an outer structure is disposed the distal section and the inner coil.

Response to Arguments

16. Applicant's arguments filed February 28, 2005 regarding the rejection of claims 43-50, 52 and 53 under 35 U.S.C. 102(e) as being anticipated by Rooney et al. ('105) have been fully considered but they are not persuasive. Applicant contends that Rooney et al. fails to teach that the proximal portion of the coil is connected to a distal portion of the core wire and that a polymer sheath or outer structure extends proximally beyond the proximal region of the coil and distally beyond the distal portion of the core wire and the coil to form a tip. These arguments are not persuasive.

With regard to Applicant's argument that Rooney et al. fail to teach that the proximal portion of the coil is connected to a distal portion of the core wire, claims 43 and 47 of the present application includes the transitional phrase "comprising" which is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. The Examiner respectfully submits that the coil of Rooney et al. is connected to the entire length of the core

wire, inclusive of the distal portion, by being wrapped around the core (see column 3, lines 52-57) and bonded to the core (see column 4, lines 14-28).

With regard to Applicant's argument that Rooney et al. fail to teach that a polymer sheath or outer structure extends proximally beyond the proximal region of the coil and distally beyond the distal portion of the core wire and the coil to form a tip, claims 43 and 47 of the present application includes the transitional phrase "comprising" which is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. The Examiner respectfully submits that Rooney et al. teach an outer structure formed by a pair of polymeric sheathes. A first polymer sheath (40) extends distally beyond the distal portion of the core wire and the distal region of the coil to form a tip (see figures 1 and 2). A second polymer sheath is formed by a polymer coating that coats the entire length of the guidewire (see column 5, lines 10-13), such that the second polymer sheath will extend proximally beyond the proximal region of the coil.

17. Applicant's arguments with respect to claims 1, 35, 39, 40 and 42, as well as the claims depending therefrom, have been considered but are moot in view of the new ground(s) of rejection. Regarding claims 1, 35 and 39, Applicant contends that the combination of Eder et al. and Sahatjian et al. fails to teach a connector comprising a metal alloy having a Unified Numbering System (UNS) designation of N006625 or N10276, or a nickel-molybdenum alloy designated B-2. Regarding claim 40, Applicant contends that the combination of Eder et al. and Sahatjian et al. fails to teach a joining means including a connector member comprising a metal or metal alloy different from the metal or metal alloy of the proximal section and different from the linear elastic nickel-titanium alloy of the distal section. Regarding claim 42, Applicant

contends that the combination of Eder et al. and Sahatjian et al. fails to teach that a connector comprising a nickel-chromium-iron alloy connects the proximal and distal sections. These arguments have been fully considered, but are moot in view of the new grounds of rejection citing either the combination of Abrams et al. and Sahatjian et al. or Jafari and Sahatjian et al. set forth hereinabove.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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May 25, 2005